From: PETERSON Jenn L
To: Eric Blischke/R10/USEPA/US@EPA
Subject: RE: LWG proposal to use RSET toxicity bioassay interpretation criteria
Date: 04/30/2008 12:19 PM

Eric,

I am on my way out the door for the meeting. I think there may be some slight differences in interpretative criteria between the two (RSET is 10 and 25% and we may be 10, 20 and 30), but the main differences are the one hit / two hit decision criteria (which is really a management decision) and the comparison to reference (integrating risk assessment and management). I agree with your approach - I think we should stick with what we have or fully discuss the implications of the switch before a decision is made.

-Jennifer

-----Original Message-----
From: Blischke.Eric@epamail.epa.gov
[mailto:Blischke.Eric@epamail.epa.gov]
Sent: Wednesday, April 30, 2008 11:08 AM
To: Robert W. Gensemer
Cc: shephard.burt@epa.gov; Goulet.Joe@epamail.epa.gov; PETERSON Jenn L; Humphrey.Chip@epamail.epa.gov
Subject: Re: LWG proposal to use RSET toxicity bioassay interpretation criteria
Importance: High

Ok - since I am not getting any response to my inquiries and because we need to be ready to discuss this in 2.5 hours from now, here is my take. Can someone respond to my questions presented in italics below?

It sounds to me that the RSET approach defines one hit failures for a number of tests. This failure determination is based on a comparison to reference toxicity testing. Both mortality and biomass are considered. Mean mortality differences range from 15 - 25 % difference from reference. The difference also needs to be statistically significant. The one hit criteria is a 40% reduction in biomass compared to a reference location.

I get this. What I do not understand is how this relates to our status and trends analysis presented in the problem formulation - i.e., how does this compare to the effects level 0, 1, 2, and 3 presented in the problem formulation. Can someone please provide a succinct answer to this?

For the two hit failure, the RSET process is less clear to me. It seems possible to infer that if we see a statistically significant increase in mortality and a statistically significant decrease in biomass, this would qualify as a two-hit failure.

Please confirm for me that this is a correct interpretation.

The RSET approach is premised on a comparison to reference. I understand that the status and trends is based on a comparison to negative control.

Please confirm that this is correct.

We have reference toxicity samples from Round 2 but not Round 3B.

Is this a fatal flaw in application of the RSET approach?

I think the bottom line for me, is are we comfortable going with a comparison to reference vs. a comparison to control (if my assumptions are correct)? As with many things on the PH risk assessment, we have requested the "raw" risk values and will leave interpretation to the FS. We see this in how we are dealing with background and hilltopping in going from a PRG to an RG. It seems to me that incorporating reference sites into the bioassay interpretation deviates from this approach. This may be what John Malek was getting at when he indicated that there is a certain element of risk management in the RSET approach.

Does anyone disagree with my interpretation?

Please get back to me soon.

Thanks, Eric

"Robert W. Gensemer" <rgensemer@parametrix.com>		To
04/29/2008 03:41 PM	Joe Goulet/R10/USEPA/US@EPA, Burt Shephard/R10/USEPA/US@EPA, Jennifer Peterson <peterson.jennifer@deq.state.or.us>	cc
	Eric Blischke/R10/USEPA/US@EPA	Subject
		LWG proposal to use RSET toxicity

bioassay interpretation criteria

Joe et al: After reviewing both the 2006 RSET report and the proposed changes that Helle sent us last week, I am struggling to find support for LWG's proposal to use the RSET guidelines vs. those used in our problem formulation (70/80/90% control-adjused response thresholds or the "status and trends" approach). First and foremost, the RSET thresholds depend directly on use of toxicity tests from reference sediments. What "reference" sediments would LWG propose using? Do we even have any at this site besides negative controls or tests in artificial "reference" sediments? The latter are not the same as a site reference (e.g., upstream of the site), but you guys know these data better than I do.

Second, the revised guidance has nothing to do with "1-hit 2-hit" decisions, best I can tell. Instead they use "SL1 and SL2" thresholds based on set differences between test and reference sediment responses (if statistically different from controls). That makes more sense to me that the 1-hit vs. 2-hit thresholds, simply because the levels are based on a percent difference that is easy to see and communicate--if the difference between test and control sediments is relatively large (e.g., SL2), then this is a more "severe" toxicity response. Makes sense. Whereas I'm still confused which is the more conservative response: 1-hit or 2-hit? Maybe I'm just dense...I'm sure I'll eventually sort that out if I read it through a few more times, but its pretty cryptic on the first and second read. Regardless of which RSET approach they are suggesting we use, without some further information on how LWG would intend to use a "reference" sediment, its unclear to me how the SL1 or SL2 thresholds would be used in the BERA risk characterization for this line of evidence.

Part of John's arguments in favor of using the RSET approach was, I think, that variance in the empirical toxicity data could be better explained, or the tox predictive models worked better. I can't recall which it was. Anyway, although improved explanatory power is a good thing, its not the only thing--mechanism and biological reality count too. Do the "improved" toxicity predictors make sense from a biological point of view? Even if we could predict toxicity better with an Amtrak train schedule I would still not recommend using it (to provide an extreme example).

What have you heard from others, Burt and Joe? Does this approach have more merit than I can come up with so far? I'm open to considering it, but so far, I'm not convinced. -Bob

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